IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

DANNY A. TZAKIS and
DIANE TZAKIS,

Plaintiffs, OPINION AND ORDER

v. 19-cv-545-wmc

WRIGHT MEDICAL TECHNOLOGY, INC.,

Defendant.

Plaintiffs Danny and Diane Tzakis brought this lawsuit following a 2017 surgery to remedy the alleged failure of his previously implanted, Profemur Total Hip System manufactured by Defendant Wright Medical Technology, Inc. (the "Profemur Device" or "the Device"). Among other claims, plaintiffs allege fraudulent and strict liability misrepresentation by concealment and omission, as well as negligent misrepresentation. Pending before this court is defendant's motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that plaintiffs' fraudulent misrepresentation claims fail (1) under the heightened pleading requirements of Rule 9(b) and (2) to plead reliance adequately. Alternatively, defendant asserts that the learned intermediary doctrine shields defendant from liability altogether. (Dkt. #15.) For the reasons set forth below, defendant's motion will be denied.

FACTS[1]

A. Background

In July 2007, Danny Tzakis underwent a total hip replacement surgery at Meriter Hospital in Madison, Wisconsin. (Am. Compl. (dkt. # 14) ¶ 56.) Defendant Wright designed, manufactured, marketed, and sold the prosthetic hip -- the Profemur Device -- that was implanted by the surgeon. (*Id.* ¶¶ 56, 61-62.) In September 2017, that Device fractured into two pieces, requiring a two-stage surgery to remedy. (*Id.* ¶¶ 1-2, 59-60, 64-66.)

B. Wright's Profemur Device and Promotional Materials

In 1999, Wright Medical acquired Cremascoli Ortho ("Cremascoli"), a European company that had designed and manufactured artificial hip devices since approximately 1985. (*Id.* ¶ 11.) In December 2000, the FDA began permitting defendant to distribute the Profemur Device in the United States pursuant to the "Section 510(k) Premarket Notification Process." (*Id.* ¶ 12.) Still, plaintiffs allege that the FDA never considered or approved the *safety* of the Profemur Device; instead, it only concluded that the Device was "substantially equivalent" to an already legally marketed device. (*Id.* ¶ 13.)

Between 2002 and 2005, defendant allegedly distributed marketing and promotional materials that claimed: "[n]one of the [Devices] has experienced a clinical failure since their inception"' and the Device "guarantees: Structural reliability, Absence of

[1] The following factual summary is derived from those allegations set forth in the pleading when viewed in a light most favorable to plaintiff and drawing all reasonable inferences in favor of plaintiff.

significant micromovement, [and] Absence of fretting corrosion." (*Id.* ¶ 18.) Additionally, defendant released "Instructions for Use" ("IFU"), which accompanied the Device from the time of its introduction into the United States in 2001 through at least 2008. (*Id.* ¶ 35.) The IFU states, in particular, that the Device was not suitable for use in "obese" patients, "where obesity is defined as three times normal body weight." (*Id.)*

The complaint further alleges that defendant received notice of clinical failures of Profemur Devices in European patients before its introduction into the U.S., but did not disclose this information to the FDA when filing for its initial 501(k) Premarket Notification application. (*Id.* ¶¶ 22, 23.) On or about April 19, 2005, Wright Medical reported to the FDA a Profemur Device failure for the first time. (*Id.* ¶ 28.) On December 1, 2008, it also released a "Safety Alert" to certain medical professionals advising that Wright Medical had "received reports of 43 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports." (*Id.* ¶ 33.) According to plaintiffs, there have now been more than 800 Device failures reported, and the failure rate for the long modular neck version, which was implanted in Mr. Tzakis, is approximately eight times the failure rate of the short modular neck version of the Device. (*Id.* ¶¶ 30, 32.)

C. Mr. Tzakis's Device Implant and Revision Surgery

Mr. Tzakis had a left hip arthroplasty on or about July 9, 2007, at which time the long modular neck version of the Profemur Device was implanted. (Am. Compl. (dkt. #14) ¶ 56.) Subsequently, Mr. Tzakis used his device in a normal and expected manner.

(*Id.* ¶ 60.) However, on or about September 30, 2017, a part of the Device failed, causing it to fracture into two pieces while Mr. Tzakis "was performing a normal and expected activity of daily living, i.e. walking." (*Id.* ¶¶ 59, 60.) That same day, Mr. Tzakis was taken to the emergency room at Meriter Hospital in Madison, Wisconsin. (*Id.* ¶ 63.) Five days later, the fractured Device was surgically removed by Dr. Matt Squire at University of Wisconsin Hospital and Clinics in Madison, Wisconsin. (*Id.* ¶ 64.) Due to complications associated with the surgery, Dr. Squire was unable to complete the procedure on October 5 and Mr. Tzakis was transferred to the University of Wisconsin Hospital and Clinics Intensive Care Unit. (*Id.* ¶ 65.) Dr. Squire completed the second stage of the surgery on October 6, 2017. (*Id.* ¶ 66.)

Among other claims, plaintiffs allege that Wright fraudulently misrepresented the safety of the Device by concealing and omitting material information relating to the safety of the Profemur Device. (*Id.* ¶ 1.) They further allege that their healthcare providers and they relied on defendant's misrepresentations and, as a result, Mr. Tzakis endured "pain and suffering," "debilitating lack of mobility," and "increased risk of complications and death from surgery." (*Id*.) Plaintiffs seek general damages for personal injuries, pain and suffering, and all past, current, and future medical expenses, as well as punitive damages to deter similar conduct in the future. (*Id.* ¶ 88.)

OPINION

Defendant seeks dismissal of plaintiffs' claims for fraudulent, strict liability and negligent misrepresentation by concealment and omission. However, dismissal is warranted only if no recourse could be granted under any set of facts consistent with the

allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 (2007). As this court has emphasized before, the motion to dismiss phase of proceedings "is not an opportunity for the court to find facts or weigh evidence." *My Health, Inc. v. Gen. Elec. Co.*, No. 15-CV-80-JDP, 2015 WL 9474293, at *2 (W.D. Wis. Dec. 28, 2015). When reviewing a motion to dismiss under Rule 12(b)(6), the court must accept all well-pleaded factual allegations as true and draw all inferences in the light most favorable to the non-moving party. *Pugh v. Tribune Co.*, 521 F.3d 686, 692 (7th Cir. 2008). Defendant argues that plaintiffs' claims should be dismissed because: (1) the claims fail to satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b); (2) the plaintiffs have failed to sufficiently plead reliance; and (3) defendant is shielded from liability under the learned-intermediary doctrine. The court addresses each of these arguments in turn below.[2]

I. Pleading Deficiencies

Defendant first argues that "Plaintiffs fail to plead the [misrepresentation] claims with the requisite heightened standard under Federal Rule of Civil Procedure 9(b)." (Mot. to Dismiss Br. (dkt. #16) 2.) Generally, defendant argues that plaintiffs' complaint contains vague claims and conclusory allegations that fail to meet the requirements for pleading fraudulent misrepresentation under Seventh Circuit precedent. In response, plaintiffs argue that they are not required to plead the "who, what, when, where, and how"

[2] Federal law controls the issue of whether plaintiffs' complaint satisfies the Federal Rules of Civil Procedure; plaintiffs' substantive misrepresentation claims are assessed under and subject to Wisconsin law. *Ward v. Soo Line R.R. Co.*, 901 F.3d 868, 880 (7th Cir. 2018); *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938).

of the alleged fraud. (Pl. Response Br. (dkt. #17) 11 (citing *Liesch v. Zimmer Biomet Holdings, Inc.*, No. 17-CV-1036, 2017 WL 10646442, at *3 (E.D. Wis. Nov. 29, 2017)).)

To begin, Federal Rule of Civil Procedure 9(b) requires that in alleging fraud, "a party must state with particularity the circumstances constituting fraud." In order to satisfy this heightened pleading standard, a "plaintiff may need to perform pre-complaint investigation to provide the 'who, what, when, where, and how' underlying the alleged fraud." *Karnes v. C.R. Bard, Inc.*, No. 18-CV-931-WMC, 2019 WL 1639807, at *6 (W.D. Wis. Apr. 16, 2019) (citing *Webb v. Frawley*, 906 F.3d 569, 576 (7th Cir. 2018)). The relevance of pleading the "who, what, when, where, and how" is case-specific, however, "and the Seventh Circuit has warned against 'tak[ing] an overly-rigid view of th[at] formulation.'" *Karnes*, 2019 WL 1639807 at *6 (quoting *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011)). Having said that, "Rule 9(b)'s 'particularity' requirement applies to plaintiffs' claim for fraudulent concealment." *Karnes*, 2019 WL 1639807 at *6.

Here, defendant argues that this court should construe the "particularity" requirements of Rule 9(b) strictly, asserting in particular that plaintiffs' pleading falls short of this standard, since "at no point," do they "allege who made the representations, to whom they were made, or the date of the representations." (Mot. to Dismiss Br. (dkt #16) 5.) Defendant's demanding reading of Rule 9(b)'s requirements is inconsistent with Seventh Circuit precedent, at least with respect to claims of fraudulent concealment and material omission. Not only must this court "accept all well-pleaded factual allegations as true and draw all inferences in the light most favorable to the non-moving party," in

considering a Rule 12(b)(6) motion, *Liesch*, 2017 WL 10646442, at *2, but the Seventh Circuit has explained that the purpose of the heightened pleading requirements in fraud cases "is to force the plaintiff to do more than the usual investigation before filing his complaint," meaning the requirements of Rule 9(b) "are relaxed when specific details are within defendants' exclusive knowledge or control." *Id.* (citing *Jepson, Inc. v. Makita Corp.*, 34 F.3d 1321, 1328) (7th Cir. 1994)).

Under Wisconsin law, to prove a claim of fraudulent misrepresentation by concealment and omission, a plaintiff must establish: (1) defendant's failure to disclose a material fact; (2) defendant's intent to defraud; and (3) plaintiff's reliance on defendant's disclosures. *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998) (citing *Goerke v. Vojvodich*, 67 Wis.2d 102, 226 N.W.2d 211 (1975); *Ollerman v. O'Rourke Co., Inc.*, 94 Wis.2d 17, 26 & 43 n.26, 288 N.W.2d 95 (1980)). Applying these requirements in *Karnes*, plaintiffs were deemed to have adequately pleaded fraudulent concealment by first alleging that a medical device manufacturer falsely represented that its device was "safe and effective." 2019 WL 1639807, at *6. Second, plaintiffs there claimed that the defendant "'knowingly made false claims in documents and marketing materials about the safety and quality of the [device],' choosing to conceal the product's nature 'to mislead Plaintiff, her physicians, hospitals, and healthcare providers' so that they would use the device." *Id.* Third and finally, plaintiffs alleged that both they and their healthcare providers relied on the information from defendant, which omitted material concerns about the device. *Id.*

So, too, plaintiffs here have pleaded the elements of their fraudulent misrepresentation by concealment and omission claim with sufficient particularity. First, plaintiffs allege that defendant failed to disclose a material fact: much like in *Karnes*, they allege that "[d]efendant omitted, concealed or suppressed material information and facts regarding the safety and performance of [the Device], including, but not limited to: (a) [t]hat the Device had an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use," and (b) that the Device "had an unacceptably high rate of failures requiring revision surgery." (Am. Compl. (dkt. # 14) ¶ 143.) At least by inference, plaintiffs further claim that defendant distributed marketing and promotional materials between 2002 and 2005 which falsely claimed that "[n]one of the [Devices] has experienced a clinical failure since their inception," and that the Device "guarantees: Structural reliability, Absence of significant micromovement, [and] Absence of fretting corrosion." (*Id.* ¶ 18.)

Second, plaintiffs have alleged defendant's intent to defraud. Specifically, the complaint claims that defendant "purposefully downplayed and understated the serious nature of the risks associated with the use of [the Device] in order to increase and sustain sales and to induce Plaintiff and Plaintiff's health care providers to use the Device and implant the Device in Plaintiff." (*Id.* ¶ 144.)

Third, plaintiffs claimed detrimental reliance on defendant's fraudulent disclosures and material omission just like the plaintiffs in *Karnes*, alleging that they and their healthcare providers: relied on defendant's incomplete and inaccurate representations regarding the safety and risks associated with using the Device (*id.* ¶ 153); and "would not

have selected the Device for use in Plaintiff and Plaintiff would not have consented to have the Device implanted in his body," if the allegedly concealed facts had been disclosed (*id.* ¶ 154).

Following Seventh Circuit precedent, therefore, this court will decline defendant's request to take an "overly rigid view of the formulation" for pleading the "who, what, when, where, and how" under Rule 9(b). *Pirelli Armstrong Tire Corp.*, 631 F.3d at 442. This would seem especially appropriate given that plaintiffs have conducted more than the usual pre-complaint investigation to satisfy the particularity requirement under Rule 9(b). *Liesch*, 2017 WL 10646442, at *2. Accordingly, plaintiff's claims of fraudulent misrepresentation by concealment and omission may proceed past the pleading stage.

As a separate matter, defendant argues that plaintiffs have failed to adequately demonstrate their reliance to succeed on a claim of fraudulent misrepresentation by concealment and omission. *Staudt*, 16 F. Supp. 2d at 1031; *Ollerman*, 94 Wis.2d at 26, 43 n.26. Specifically, defendant relies on *Staudt* to support its argument that plaintiffs have not efficiently alleged reliance. In *Staudt*, the court granted summary judgment for defendant on claims that it had fraudulently concealed information and plaintiffs had relied on defendant's misrepresentations to their detriment. *Staudt*, 16 F. Supp. 2d at 1032. The court explained that "the uncontested facts show that . . . no representations were made to the plaintiff about the [device] which would be used in his surgery," and that plaintiffs did not "produc[e] a shred of evidence to support the contention that [defendant] made any representations . . . regarding the safety of its devices or that [plaintiffs] relied on such representations." *Id.*

In a similar case, the Seventh Circuit granted summary judgment for defendant medical device manufacturer against a plaintiff who was injured after their knee implant failed. *In re Zimmer, NexGen Knee Implant Prods. Liab. Lit.*, 884 F.3d 746, 751 (7th Cir. 2018). Importantly, the court reasoned that "summary judgment was appropriate because no evidence show[ed] that 'if properly warned, [plaintiff's doctor] would have altered [his] behavior and avoided injury.'" *Id.* at 754 (citing *Kurer v. Parke, Davis & Co.*, 272 Wis. 2d 390, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004)). Notably, however, the motion before this court is *not* for summary judgment, as it was in both *Zimmer* or *Staudt*, but rather a motion to dismiss under Rule 12(b)(6). Under notice pleading standards, plaintiffs here have done far more than necessary to plead their reliance -- and their healthcare providers -- on the defendant's fraudulent concealment and omission of material information.

Again, the complaint alleges that defendant distributed marketing and promotional materials between 2002 and 2005, which claimed that (1) "[n]one of the [Devices] has experienced a clinical failure since their inception," and (2) the Device "guarantees: Structural reliability, Absence of significant micromovement, [and] Absence of fretting corrosion." (*Id.* ¶ 18.) The complaint further asserts that these representations were false because defendant was aware of clinical failures of Profemur Devices that had been implanted in patients in Europe before 2001. (Am. Compl. (dkt. # 14) ¶¶ 18, 22.) Plaintiffs further allege that defendant did not inform orthopedic surgeons in the United States known by defendant to have implanted the Device of any reports or concerns about fractures of the Device until the December 1, 2008 "Safety Alert." (*Id.* ¶ 33.) Moreover,

the "Safety Alert" expressly acknowledges that defendant had in fact received reports of *43* Device failures as of November 21, 2008. (*Id.*)

Plaintiffs also claim that they and their healthcare providers relied on defendant's representations as to the safety and performance of the Profemur Device when selecting, recommending, and implanting it. (*Id.* ¶ 170.) Significantly, in contrast to *Zimmer*, plaintiffs also allege that if the concealed information had been disclosed to plaintiffs or their healthcare providers, the providers would not have selected the Device for Mr. Tzakis's use and plaintiffs would not have consented to have the Device implanted in his body. (*Id.* ¶ 171); *see also Karnes*, 2019 WL 1639807, at *7 (plaintiffs sufficiently pleaded reliance when they claimed that their "physician would not have implanted the product in plaintiff" if they had known about defendant's misrepresentations.); *Kurer v. Parke, Davis, & Co.*, 272 Wis.2d 390, 679 N.W.2d 867, 876 (2004).

Accepting the facts stated in the complaint as true, plaintiffs sufficiently pleaded reliance in satisfaction of Rule 9(b). Moreover, unlike the plaintiffs in *Staudt* and *Zimmer*, plaintiffs have already provided more than "a shred of evidence" to support their contention that defendant did, in fact, fraudulently conceal or omit material information. *Staudt*, 16 F. Supp. 2d at 1032. Regardless, like *Karnes*, plaintiffs have alleged misrepresentation by concealment and omission and demonstrated their reliance the defendant's misrepresentation. Therefore, plaintiffs may proceed past the pleading stage as to their fraudulent concealment claims.

II. Learned Intermediary Doctrine

Finally, the learned intermediary doctrine protects medical device manufacturers from liability if they fulfill their duty to warn of their products' risks by informing the prescribing physician of those risks. *In re Zimmer, NexGen Knee Implant Prods. Liab. Lit.*, 884 F.3d 746, 751 (7th Cir. 2018). In *Zimmer*, the Seventh Circuit observed that though not settled law, "there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases like this one involving a surgical implant." *Id.* at 752. As this court stated in *Karnes*, the reasoning of the learned intermediary doctrine is sound, especially in the case of surgical implants. 2019 WL 1639807, at *7; *see also Zimmer*, 884 F.3d at 752.[3]

Assuming its application under Wisconsin law, defendant argues that it is shielded from liability under the learned intermediary doctrine because defendant had no duty to warn plaintiffs directly of any risk attendant with its devices. (Mot. to Dismiss Br. (dkt. # 16) 9.) On the other hand, plaintiffs argue that the learned intermediary doctrine does not preclude fraud claims, "particularly claims alleging that a device manufacturer provided misleading information to or withheld information from, the learned intermediary, resulting in harm to patient." (Pl. Response Br. (dkt. # 17) 18.)

As noted, the Seventh Circuit explained that "[t]he doctrine holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the

[3] Wisconsin appellate courts have still not considered the doctrine's application, which leaves this court with no guidance beyond *Zimmer*. *See Karnes*, 2019 WL 1639807, at *7 (citing *Zimmer*, 884 F.3d at 751).

product's risks by informing the prescribing physician of those risks." *Zimmer*, 884 F.3d at 751. Here, plaintiffs allege that defendant *failed* to "warn physicians . . . of the [Profemur Device's] unreasonably high propensity for corrosions, fretting and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device." (Am. Compl. (dkt. # 14) ¶ 125.) If true, then the doctrine would have no application. Regardless, accepting all well-pleaded factual allegations in the complaint as true and drawing all inferences in the light most favorable to plaintiffs as the non-moving party, it would be improper to dismiss plaintiffs claims of fraudulent misrepresentation by concealment and omission under the learned intermediary doctrine at the pleading stage.

ORDER

IT IS ORDERED that defendant's motion to dismiss (dkt. #15) is DENIED.

Entered this 27th day of February, 2020.

BY THE COURT:

/s/

WILLIAM M. CONLEY
District Judge